ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): **October 31, 2012**

Acorda Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**000-50513**	**13-3831168**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

420 Saw Mill River Road, Ardsley, NY	**10502**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(914) 347-4300**

Not Applicable
Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition

On October 31, 2012, Acorda Therapeutics, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2012. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K, and incorporated by reference into this Item 2.02.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	*Description*
99.1	Press Release dated October 31, 2012

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Acorda Therapeutics, Inc.

October 31, 2012

By: /s/ David Lawrence
Name: David Lawrence
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated October 31, 2012

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Reports Third Quarter 2012 Financial Results

- AMPYRA ® (dalfampridine) Third Quarter Net Revenue of $69.8 Million
- Combined Third Quarter ZANAFLEX Franchise and ex-U.S. FAMPYRA ® Royalty Revenue of $5.3 Million

ARDSLEY, N.Y. – October 31, 2012 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced its financial results for the third quarter ended September 30, 2012.

“We were pleased with AMPYRA’s performance in the third quarter, with net sales of $69.8 million. This was an approximate 5% increase over the second quarter of 2012 and a 28% increase over the third quarter of 2011,” said Ron Cohen, M.D., Acorda Therapeutics’ President and CEO. “Our top priority is to continue to maximize the AMPYRA franchise, both in its existing indication as well as potential indications in addition to multiple sclerosis. We also have established an exciting pipeline behind AMPYRA, through disciplined investment in both our existing assets and in-licensing of promising neurological agents. We believe that this strategy positions Acorda to deliver significant shareholder value.”

FINANCIAL RESULTS
The Company reported GAAP net income of $9.6 million for the quarter ended September 30, 2012, or $0.24 per diluted EPS, including share-based compensation charges totaling $5.6 million. GAAP net income in the same quarter of 2011 was $18.9 million, or $0.47 per diluted EPS, including share-based compensation charges totaling $5.1 million, net milestone revenue of $23.3 million relating to Biogen Idec's receipt of conditional approval from the European Commission for FAMPYRA and accounting adjustments totaling $15.5 million relating to ZANAFLEX CAPSULES due to the patent infringement trial decision.

Non-GAAP net income, before share-based compensation charges, for the quarter ended September 30, 2012 was $15.2 million, or $0.38 per diluted EPS. Non-GAAP net income in the same quarter of 2011, before share-based compensation charges, net milestone revenue and accounting adjustments relating to ZANAFLEX CAPSULES due to the Apotex patent infringement trial court decision, was $16.2 million or $0.40 per diluted EPS.

AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg net revenue - For the quarter ended September 30, 2012, the Company reported AMPYRA net revenue of $69.8 million, compared to $54.7 million in net revenue for the same quarter in 2011. AMPYRA revenue is recognized following shipment of the product from the Company’s distribution facility to its network of specialty pharmacies.

The Company is reiterating 2012 AMPYRA net sales guidance of $255-$275 million.

ZANAFLEX CAPSULES ® (tizanidine hydrochloride), ZANAFLEX ® (tizanidine hydrochloride) tablets and authorized generic tablets net revenue and royalties - For the quarter ended September 30, 2012, the Company reported combined net revenue from ZANAFLEX CAPSULES and ZANAFLEX tablets sales of

$1.9 million; revenue from the sale of authorized generic tizanidine hydrochloride capsules to Watson Pharmaceuticals, Inc. totaled $0.5 million and royalties from Watson for the sale of authorized generic tizanidine hydrochloride capsules were $1.4 million, for combined total net revenue of $3.8 million. Combined net revenue from ZANAFLEX CAPSULES and ZANAFLEX tablets sales were $10.7 million for the same quarter in 2011.

ZANAFLEX revenue is recognized using a deferred revenue recognition model, meaning ZANAFLEX CAPSULES and ZANAFLEX tablets shipments to wholesalers are recorded as deferred revenue and only recognized as revenue when end-user prescriptions of ZANAFLEX CAPSULES and ZANAFLEX tablets are reported. Authorized generic product sold to Watson is recorded as sales when shipped.

ZANAFLEX CAPSULES and ZANAFLEX tablets shipments - Total ZANAFLEX CAPSULES and ZANAFLEX tablets shipments for the quarter ended September 30, 2012 were $3.0 million, compared to total shipments of $14.1 million for the same quarter in 2011. The decrease is due to the launch of generic versions of ZANAFLEX CAPSULES during the first quarter of 2012.

FAMPYRA ® (prolonged-release fampridine tablets) royalties - For the quarter ended September 30, 2012, the Company reported FAMPYRA royalties from sales outside of the U.S. of $1.5 million, compared to $0.3 million for the same quarter in 2011.

The Company continues to expect combined ZANAFLEX franchise (including revenues from authorized generic capsules) and ex-U.S. FAMPYRA royalty revenue of at least $25 million for 2012.

Cost of sales for the quarter ended September 30, 2012 were $14.8 million, compared to $26.7 million for the same quarter in 2011. Included in cost of sales for the quarter ended September 30, 2012 was $0.5 million in cost of authorized generic tizanidine hydrochloride capsules sold to Watson. The decrease in cost of sales was primarily due to the $14.1 million in accounting adjustments in 2011 related to the Apotex patent infringement trial court decision.

Research and development (R&D) expenses for the quarter ended September 30, 2012 were $12.0 million, including $1.4 million of share-based compensation, compared to $9.1 million including $1.5 million of share-based compensation for the same quarter in 2011. R&D expenses for the quarter ended September 30, 2012 included costs related to AMPYRA post-marketing studies and life cycle management programs, and the development of the Company's pipeline products, including clinical trial expenses for Glial Growth Factor 2 (GGF2) and AMPYRA proof-of-concept cerebral palsy and post-stroke deficits studies.

The Company is updating R&D expense guidance for the full year 2012 downward to approximately $45 million as a result of changes in timing of several R&D programs. This guidance excludes share-based compensation and future expenditures related to the potential acquisition of Neuronex and its diazepam nasal spray product.

Sales, general and administrative (SG&A) expenses for the quarter ended September 30, 2012 were $40.1 million, including $4.2 million of share-based compensation, compared to $34.7 million including $3.5 million of share-based compensation for the same quarter in 2011.

The Company continues to expect SG&A expenses for the full year 2012 to be $145-$160 million, excluding share-based compensation charges.

For the quarter ended September 30, 2012, the Company closed in a strong financial position with cash, cash equivalents and short-term and long-term investments of $318.7 million, an increase of $15.7 million over the second quarter of 2012.

AMPYRA UPDATE

- In August, the Company reported top-line data from a post-marketing commitment study evaluating a 5 mg dose of dalfampridine-ER to improve walking in people with MS. The study failed to confirm efficacy of the 5 mg dose.

PIPELINE UPDATE

- The first part of the AMPRYA cerebral palsy (CP) proof-of-concept trial has been completed. This 10-person, single-dose safety phase of the study detected no safety signals that would prevent additional study of the drug in the treatment of CP. The Company is currently enrolling the second part of the trial, a multi-dose study including 20 people with CP, to evaluate both safety and efficacy of AMPYRA. The Company expects to announce results of the trial by mid-2013.
- Enrollment in the Glial Growth Factor 2 (GGF2) Phase 1 clinical study in heart failure has been completed. This was a dose-escalating trial designed to test the maximum tolerated single dose. The Company expects to complete data analysis by the end of the year, and plans to present findings in a peer-review setting. The Company will discuss the data with the U.S. Food and Drug Administration (FDA) before proceeding to a multiple dose study.
- The Company submitted the Phase 2 clinical trial protocol for AC105 for acute treatment of spinal cord injury to the FDA for review, and is continuing preparations to initiate the trial.
- The Company submitted an Investigational New Drug (IND) application to the FDA for rHIgM22, a remyelinating antibody for the treatment of multiple sclerosis. The FDA has requested additional information, and the Company expects to submit a response by the end of the year. The Company plans to begin a Phase 1 study following FDA review of the study protocol.
- In October, the Company presented preclinical data at the Society for Neuroscience meeting that showed rHIgM22 promotes expression of myelin-associated genes following injury to myelin, confirming earlier work showing rHIgM22 stimulates remyelination in preclinical models of demyelination.
- In August, the Company presented preclinical data at the World Meeting on Sexual Medicine that showed treatment with GGF2 improved erectile dysfunction (ED) following cavernous nerve injury. Approximately 270,000 prostate surgeries are performed in the United States each year, and ED caused by cavernous nerve damage is a common complication of this surgery.

CORPORATE UPDATES

- In October, the Company named Jane Wasman as President, International. In this role, Ms. Wasman will lead the Company's efforts to identify and launch in-licensing and commercial opportunities outside the United States. She will also be responsible for managing Acorda's collaboration with Biogen Idec (Nasdaq: BIIB) in their international development and commercialization of FAMPYRA.
- In October, the Company was added to the S&P SmallCap 600 Index.
- The Company's healthcare professional marketing campaign and AMPYRA.com website received industry awards from Medical Marketing & Media, and International Academy of the Visual Arts.
- The Company received two Telly Awards for online videos produced for, and posted to, the Company's various web-based properties.

This press release includes financial results prepared in accordance with accounting principles generally accepted in the United States (GAAP), and also certain historical and forward-looking non-GAAP financial measures. In particular, Acorda has provided income, adjusted to exclude share-based compensation charges, the payments associated with Neuronex in 2012, the net milestone revenue relating to Biogen Idec's receipt of conditional approval from the European Commission for FAMPYRA in 2011, the ZANAFLEX CAPSULES adjustments due to the Apotex patent infringement trial court decision in 2011 and the AC105 license fee in 2011. Also, Acorda has provided projected amounts of research and development (R&D) and sales, general, and administrative (SG&A) expenses excluding share-based compensation charges and future expenditures related to the potential acquisition of Neuronex and diazepam nasal spray. These non-GAAP financial measures are not an alternative for financial measures prepared in accordance with GAAP. However, we believe the presentation of these non-GAAP financial

measures when viewed in conjunction with our GAAP results, provide investors with a more meaningful understanding of our ongoing and projected operating performance because they exclude non-cash charges that are substantially dependent on changes in the market price of our common stock and expenses and income that do not arise from the ordinary course of our business. We believe these non-GAAP financial measures help indicate underlying trends in the company's business and are important in comparing current results with prior period results and understanding projected operating performance. Also, management uses these non-GAAP financial measures to establish budgets and operational goals, and to manage the company's business and to evaluate its performance. A reconciliation of the historical non-GAAP financial results presented in this release to our GAAP financial results is included in the attached financial statements.

WEBCAST AND CONFERENCE CALL

Ron Cohen, President and Chief Executive Officer, and David Lawrence, Chief Financial Officer, will host a conference call today at 8:30 a.m. ET to review the Company's third quarter 2012 results.

To participate in the conference call, please dial 800-561-2813 (domestic) or 617-614-3529 (international) and reference the access code 68426357. The presentation will be available via a live webcast on the Investor section of www.acorda.com.

A replay of the call will be available from 10:30 a.m. ET on October 31, 2012 until midnight on November 30, 2012. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 62520998. The archived webcast will be available for 30 days in the Investor Relations section of the Acorda website at www.acorda.com.

Important Safety Information

AMPYRA can cause seizures; the risk of seizures increases with increasing AMPYRA doses. AMPYRA is contraindicated in patients with a prior history of seizure. Discontinue AMPYRA use if seizure occurs.

AMPYRA is contraindicated in patients with moderate or severe renal impairment (CrCl less-than or equal to 50 mL/min); the risk of seizures in patients with mild renal impairment (CrCl 51-80 mL/min) is unknown, but AMPYRA plasma levels in these patients may approach those seen at a dose of 15 mg twice daily, a dose that may be associated with an increased risk of seizures; estimated CrCl should be known before initiating treatment with AMPYRA.

AMPYRA should not be taken with other forms of 4-aminopyridine (4-AP, fampridine), since the active ingredient is the same. Urinary tract infections were reported more frequently as adverse reactions in patients receiving AMPYRA 10 mg twice daily compared to placebo.

The most common adverse events (incidence greater-than or equal to 2% and at a rate greater than the placebo rate) for AMPYRA in MS patients were urinary tract infection, insomnia, dizziness, headache, nausea, asthenia, back pain, balance disorder, multiple sclerosis relapse, paresthesia, nasopharyngitis, constipation, dyspepsia, and pharyngolaryngeal pain.

For full U.S. Prescribing Information and Medication Guide for AMPYRA, please visit: www.AMPYRA.com .

About AMPYRA (dalfampridine)

AMPYRA is a potassium channel blocker approved as a treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed. AMPYRA, which was previously referred to as Fampridine-SR, is an extended release tablet formulation of dalfampridine (4-aminopyridine, 4-AP), and is known as prolonged-, modified, or sustained-release fampridine (FAMPYRA ®) in some countries outside the United States (U.S).

In laboratory studies, dalfampridine extended release tablets has been found to improve impulse conduction in nerve fibers in which the insulating layer, called myelin, has been damaged. AMPYRA is

being developed and commercialized in the U.S. by Acorda Therapeutics; FAMPYRA is being developed and commercialized by Biogen Idec in markets outside the U.S. based on a licensing agreement with Acorda. AMPYRA and FAMPRYA are manufactured globally by Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc, based on a supply agreement with Acorda.

AMPYRA is available by prescription in the United States. For more information about AMPYRA, including patient assistance and co-pay programs, healthcare professionals and people with MS can contact AMPYRA Patient Support Services at 888-881-1918.

AMPYRA Patient Support Services is available Monday through Friday, from 8:00 a.m. to 8:00 p.m. Eastern Time at 888-881-1918. For full U.S. Prescribing Information and Medication Guide, please visit: www.AMPYRA.com.

About Acorda Therapeutics
Acorda Therapeutics is a biotechnology company focused on developing therapies that restore function and improve the lives of people with MS, spinal cord injury and other neurological conditions.

Acorda markets AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg, in the United States as a treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an improvement in walking speed. AMPYRA is marketed outside the United States as FAMPYRA® (prolonged-release fampridine tablets) by Biogen Idec under a licensing agreement from Acorda. AMPYRA and FAMPYRA are manufactured under license from Alkermes Pharma Ireland Limited.

The Company also markets ZANAFLEX CAPSULES ® (tizanidine hydrochloride) and Zanaflex tablets, a short-acting drug for the management of spasticity. Acorda also receives sales royalties on tizanidine hydrochloride capsules, an authorized generic version of ZANAFLEX CAPSULES distributed by Watson Pharmaceutics, Inc. under its agreement with Acorda.

Acorda is developing an industry-leading pipeline of novel neurological therapies. The Company is studying AMPYRA to improve a range of functional impairments caused by MS, as well as its use in other neurological conditions, including cerebral palsy and chronic stroke. In addition, Acorda is developing clinical stage compounds AC105 for acute treatment of spinal cord injury and GGF2 for treatment of heart failure. GGF2 is also being investigated in preclinical studies as a treatment for neurological conditions such as stroke and spinal cord injury. Additional preclinical programs include rHIgM22, a remyelinating monoclonal antibody for the treatment of MS, and chondroitinase, an enzyme that encourages nerve plasticity in spinal cord injury.

Forward-Looking Statements
This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, regarding management's expectations, beliefs, goals, plans or prospects should be considered forward-looking. These statements are subject to risks and uncertainties that could cause actual results to differ materially, including our ability to successfully market and sell Ampyra in the U.S.; third party payers (including governmental agencies) may not reimburse for the use of Ampyra at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions; the risk of unfavorable results from future studies of Ampyra or from our other research and development programs, including any acquired or in-licensed programs; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain regulatory approval of or to successfully market Fampyra outside of the U.S. and our dependence on our collaboration partner Biogen Idec in connection therewith; competition, including the impact of generic competition on Zanaflex Capsules revenues; failure to protect our intellectual property, to defend against the intellectual property claims of others or to obtain third party intellectual property licenses needed for the commercialization of our products; failure to comply with regulatory requirements could result in adverse action by regulatory agencies; and the ability to obtain additional financing to support our operations. These and other risks are described in greater detail in Acorda Therapeutics' filings with the Securities and Exchange Commission. Acorda Therapeutics may not actually achieve the goals or plans described in its forward-looking statements, and investors should

not place undue reliance on these statements. Forward-looking statements made in this press release are made only as of the date hereof, and Acorda Therapeutics disclaims any intent or obligation to update any forward-looking statements as a result of developments occurring after the date of this press release.

Acorda Therapeutics, Inc.
Condensed Consolidated Balance Sheet Data
(in thousands)
(Unaudited)

	September 30, 2012	December 31, 2011
Assets		
Cash, cash equivalents, short-term and long-term investments	$ 318,664	$ 295,907
Trade receivable, net	23,227	22,828
Other current assets	18,132	13,825
Finished goods inventory	19,240	28,382
Property and equipment, net	16,437	3,858
Intangible assets, net	9,279	8,769
Other assets	5,474	5,919
Total assets	$ 410,453	$ 379,488
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other liabilities	$ 41,703	$ 45,542
Deferred product revenue	28,800	30,599
Current portion of deferred license revenue	9,057	9,057
Current portion of notes payable	1,144	1,144
Current portion of revenue interest liability	1,335	1,001
Long-term liabilities	10,197	6,266
Non-current portion of revenue interest liability	1,801	2,928
Non-current portion of deferred license revenue	70,949	77,742
Stockholders' equity	245,467	205,209
Total liabilities and stockholders' equity	$ 410,453	$ 379,488

Acorda Therapeutics, Inc.
Consolidated Statements of Operations
(in thousands, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	**2011**	**2012**	**2011**
Revenues:				
Net product revenues	$ 72,206	$ 65,420	$ 206,992	$ 187,222
Royalty revenues	2,967	347	10,557	578
Milestone revenue	-	25,000	-	25,000
License revenue	2,264	2,264	6,793	6,793
Total revenues	77,437	93,031	224,342	219,593
Costs and expenses:				
Cost of sales	14,761	26,651	40,802	50,749
Cost of milestone and license revenue	159	1,908	476	2,225
Research and development	12,031	9,088	35,690	31,804
Selling, general and administrative	40,121	34,718	123,096	112,788
Total operating expenses	67,072	72,365	200,064	197,566
Operating income	$ 10,365	$ 20,666	$ 24,278	$ 22,027
Other expense, net	(238)	(813)	(1,108)	(2,951)
Income before income taxes	10,127	19,853	23,170	19,076
Provision for income taxes	(533)	(986)	(1,185)	(1,165)
Net income	$ 9,594	$ 18,867	$ 21,985	$ 17,911
Net income per common share - basic	$ 0.24	$ 0.48	$ 0.56	$ 0.46
Net income per common share - diluted	$ 0.24	$ 0.47	$ 0.55	$ 0.45
Weighted average per common share - basic	39,463	39,100	39,412	38,940
Weighted average per common share - diluted	40,159	40,174	40,222	40,035

Acorda Therapeutics, Inc.
Non-GAAP Income and Income per Common Share Reconciliation
(in thousands, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
GAAP net income	$ 9,594	$ 18,867	$ 21,985	$ 17,911
Pro forma adjustments:				
Neuronex payments included in R&D (Note 1)	-	-	3,200	-
Collaboration milestone revenue (Note 2)	-	(25,000)	-	(25,000)
Cost of milestone revenue (Note 2)	-	1,750	-	1,750
Zanaflex Capsule adjustments (Note 3)	-	15,477	-	15,477
License agreement expense in R&D (Note 4)	-	-	-	3,000
Share-based compensation expenses included in R&D	1,354	1,532	3,682	4,122
Share-based compensation expenses included in SG&A	4,211	3,524	11,667	9,725
Total share-based compensation expenses	5,565	5,056	15,349	13,847
Total pro forma adjustments	5,565	(2,717)	18,549	9,074
Non-GAAP net income	$ 15,159	$ 16,150	$ 40,534	$ 26,985
Net income per common share - basic	$ 0.38	$ 0.41	$ 1.03	$ 0.69
Net income per common share - diluted	$ 0.38	$ 0.40	$ 1.01	$ 0.67
Weighted average per common share - basic	39,463	39,100	39,412	38,940
Weighted average per common share - diluted	40,159	40,174	40,222	40,035

Note 1: $2.0 million upfront payment and $1.2 million in R&D payments per agreement with Neuronex.
Note 2: $25 million milestone revenue relating to Biogen Idec receipt of conditional approval from the European Commission for Fampyra in Q3 2011. Based on Acorda's worldwide license and supply agreement with Elan, Elan received 7% of this milestone payment from Acorda during the same period which was recorded as cost of milestone revenue.
Note 3: Adjustments relating to Zanaflex Capsules due to Apotex patent infringement trial court decision in Q3 2011. ($13,038 Intangible asset impairment included in cost of sales, $1,020 commercial inventory reserve included in cost of sales, $1,083 PRF put/call liability adjustment included in SG&A, $336 sample inventory reserve included in SG&A).
Note 4: $3.0 million upfront expense related to licensed worldwide development and commercialization rights to a proprietary magnesium formulation from Medtronic, Inc. (AC105) included in R&D in 2011.